K061205

JUN 21 2006

Section E - 510(k) Summary

This 510(k) summary for the **Medela® Vario 8/18/ci Powered Suction Pumps** meets the requirements of 21 CFR 807.92.

1 Sponsor's Name, Address and Contact Person

Sponsor:
Medela AG
Medical Equipment
Laettichstrasse 4b
6341 Baar
Switzerland
Ph: +41 41 769 5151 ext. 228
Fax: +41 41 769 5100

Contact Person
Werner Frei
Manager Regulatory Affairs

Date Summary Prepared: April 18, 2006

2 Name of Device

Trade Name:	**Medela® Vario 8/18/ci** Secretion & Surgical Aspirator
Common Name:	Powered Suction Pump
Classification Name:	PUMP, PORTABLE, ASPIRATION (MANUAL OR POWERED) Classified Class II, per 21 CFR 878.4780
Product Code:	BTA

3 Name of the predicate Device(s)

- Medela® Basic, Median, Dominant, Vario Suction Pumps, by Medela Inc.
  K983552
- Medela® Dominant 35 c/i, by Medela AG
  K043544

4 Device Description

This notification for the **Medela® Vario 8/18/ci Suction Pumps** is for labeling change and to include additional indications. There have been no significant modifications or design changes to the currently cleared and marketed **Medela® Vario,** 510(k) No. K983552.

The **Medela® Vario 8/18/ci** Suction Pumps is a further innovative development of Medela's well-proven piston/cylinder system. With its QuatroFlex™ technology, the drive power is transferred to the four piston/cylinder modules by means of high-grade, flexible thin-films hinges. The required suction value is rapidly built-up. High suction performance and low weight are positive features of the Vario pump.

The **Medela® Vario 8/18/ci** is an AC or an AC/DC-powered portable aspirator and incorporates in its medium sized housing an AC respectively DC-motor with a flat belt power transmission to the pistons and cylinders, an ON/OFF-switch, a vacuum gauge in kPa and mmHG, a self-bleeding membrane vacuum regulator, an overflow protection device (hydrophobic filter) and connection tubing, an electric cord and an instruction manual.

The **Medela® Vario 18** "high vacuum" suction pump has a suction capacity of 18 liters per minute and a maximum vacuum up to -75 kPa (-563 mmHg). The pump is marked "low flow – high vacuum".

The **Medela® Vario 18** "medium vacuum" suction pump has a suction capacity of 18 liters per minute and a maximum vacuum up to -50 kPa (-375 mmHg). The pump is marked "low flow – medium vacuum".

The **Medela® Vario 8** "low vacuum" suction pump has a suction capacity of 8 liters per minute and a maximum vacuum up to -9 kPa (-68 mmHg). The pump is marked "low flow – low vacuum".

A variety of reusable and disposable accessories are available. A variety of disposables for thoracic drainage are also available.

5 Indications for use

The **Medela® Vario 8/18/ci Suction Pumps** are indicated for aspiration and removal of surgical fluids, tissue (including bone), gases, bodily fluids (including vomit) or infectious materials from a patient's airway or respiratory support system, either during surgery or at the patient's bedside.

Generally the **Medela® Vario 8/18/ci** is intended to be used for a variety of suctioning procedures including nasopharyngeal, tracheal, surgical, gastrointestinal and thoracic drainage (in combination with a water seal or dry seal chest drain) in either "constant" or "intermittent" mode. Especially for thoracic drainage the **Medela® Vario 8** is indicated in situations such as pneumothorax, after surgery (post operative), thorax injury, pleura effusion, pleuryempyem or other related conditions.

6 Summary of Technological Characteristics

The **Medela® Vario 8/18/ci suction pumps** are identical in construction and performance to the legally marketed device as submitted under FDA File Number K983552 - there are no technical differences which would raise new aspects regarding safety and effectiveness.
The only modifications relate to a change from lead acid to NiMH batteries and more differentiated trade names - **Medela® Vario 8** or **Medela® Vario 18** instead of **Medela® Vario** only (the number reflects the different flow rates - 8 l/min or 18 l/min).

7 Conclusion

According to the FDA Guidance „Deciding When to Submit a 510(k) for a Change to an Existing Device", the modification mentioned above does not significantly affect the safety or effectiveness of the device (e.g. a significant change or modification in design, material, chemical composition, energy source or manufacturing process). All conclusions are made by the decision making process according this guidance document.

Based upon the information presented above and in this 510(k) submission, it is concluded that the proposed **Medela® Vario 8/18/ci** powered suction pump is reliable, safe and effective for the intended use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 21 2006

Medela AG
c/o Werner Frei, Manager Regulatory Affairs
Laettichstrasse 4b
6341 Baar
Switzerland CH-6341

Re: K061205
Trade/Device Name: Medela Vario
Regulation Number: 21 CFR 878.4780
Regulation Name: Powered suction pump
Regulatory Class: II
Product Code: BTA
Dated: April 18, 2006
Received: May 8, 2006

Dear Werner Frei:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

for Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K061205

Device Name: Medela Vario

Indications For Use:
The Medela Vario 8/18/ci Suction Pumps are indicated for aspiration and removal of surgical fluids, tissue (including bone), gases, bodily fluids (including vomit) or infectious materials from a patient's airway or respiratory support system, either during surgery or at the patients bedside.

Generally the Medela Vario 8/18/ci is intended to be used for a variety of suctioning procedures including nasopharyngeal, tracheal, surgical, gastrointestinal and thoracic drainage (in combination with a water seal or dry seal chest drain) in either "constant" or "intermittent" mode. Especially for thoracic drainage the Medela Vario 8 is indicated in situations such as pneumothorax, after surgery (post operative), thorax injury, pleura effusion, pleuryempyem or other related conditions.

Prescription Use __X___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K061205